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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,180	12/12/2006	Michele Virno	289513US6PCT	6731

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EXAMINER	
WHITE, DENNIS MICHAEL	
ART UNIT	PAPER NUMBER
1797	

NOTIFICATION DATE	DELIVERY MODE
06/22/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/575,180	VIRNO, MICHELE	
	Examiner	Art Unit	
	DENNIS M. WHITE	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20,21 and 24-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20,21 and 24-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Amendment filed on 4/7/2010 is noted. Claims 20 is amended. Claims 22-23 are cancelled. Currently claims 20-21, 24-37 are pending.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 20-21, and 24-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al (US 2002/0185457) in view of Vlasselaer (USP 5,663,051).

Regarding claim 20, 24 and 26-27, Smith et al teach a centrifuge tube ("A disposable container for centrifuging and treating a fluid biological material, the container") comprising: an open top end and a closed bottom end, wherein the top end comprises a removable lid including:

a) a first opening 42;

b) a second opening 34 passed through by a second cannula 38 that can be accessed by a hypodermic needle ("hollow needle to transfer a fluid biological material into or from the container through the hollow needle") (Fig. 4);

c) a third opening 32 passed through by a third cannula 36 operationally connected to a Leur.TM. ports ("an attachment configured to receive and accommodate one end of a syringe to transfer a fluid biological material into or from the container through the third cannula"). The cannula length is at least equal to the height of the container (Fig. 8). Smith et al is silent about the first opening 42 is passed through by a first cannula that can be connected operationally to the external environment to control entry and exit of air in conjunction with transfer of a fluid biological material into or from the container and wherein the top end of the first cannula includes a removable stopper for controlling the entry and exit of air in conjunction with the transfer of a fluid biological material into or from the container.

Vlasselaer teach centrifuge tube centrifuge tube 76 having a closed top 77. The closed top will have at least one, and preferably at least two entry ports, useful for introduction and removal of sample, and for venting, as described below. In the embodiment shown, solid ridge 79 protruding upward from closed top 77 is included to form a protective barrier for the entry ports, as a safety guide for accessing compartments, and as an attachment point for a protective, removable lid for the apparatus that serves to reduce potential contamination during shipping and storage. With further reference to FIG. 6, tubing 74 is attached to tube 76 through entry port 78, adapted with fitting 80, which may be any type of locking tip adapted for sterile

connection, for example, a LuerLock.TM. syringe connector. Alternatively, fitting 80 may be a sterile septum adapted for connection with sterile fluid bags and tubes, for example a SAFSITE.TM. small wire extension set with reflux valve and Spin-Lock.TM. adaptor available from Burron Medical Inc., Bethlehem, Pa. To facilitate fluid flow into centrifuge tube 76, the tube contains air vent entry port 82. As shown, air filter 84 ("first opening 42 is passed through by a first cannula that can be connected operationally to the external environment to control entry and exit of air in conjunction with transfer of a fluid biological material into or from the container": "cannula" is sufficiently broad to read on a tube) is attached to entry port 82 to prevent contamination. The vent air filter is covered with a cap 86 ("first cannula includes a removable stopper for controlling the entry and exit of air in conjunction with the transfer of a fluid biological material into or from the container.") (col. 11 lines 3-34). Vlasselaer teach the centrifuge tube further comprising a tube with a filter ("tap") entering into the air vent entry port 82 ("tap" is sufficiently broad to read on a structure that is inserted into an entry port to provide access to the interior of a closed off container). It is desirable to provide a filter and a cap to avoid contamination through the vent.

Therefore it would have been obvious to one of ordinary skill in the art to combine the air filter and cap of Vlasselaer in the vent hole 42 of the centrifuge tube of Smith et al in order to avoid contamination to the sample being centrifuged.

Smith teaches the second cannula can be accessed by a hypodermic needle ("the hollow needle includes a connector configured to receive and accommodate one

end of a syringe") (Fig. 4), but is silent about being accessed through a pierceable membrane.

Vlasselaer teach the fitting 80 can be a sterile septum ("pierceable membrane" "the connector includes centrally a rigid straight duct covered with a flexible and pierceable sheath" "the attachment includes centrally a rigid straight duct covered with a flexible and pierceable sheath") adapted for connection with sterile fluid bags and tubes. It is desirable to provide a sterile septum to create a sealable membrane to transfer samples without contamination.

Therefore it would have been obvious to one of ordinary skill in the art to combine the sterile septum of Vlasselaer to the second cannula in order to provide a sterile entry port for the hypodermic needle.

Regarding claim 21, Smith/Vlasselaer teach the air filter 84. The filter is shaped so as to receive and accommodate one end of a syringe or an adaptor fitted onto the end of the syringe to transfer a fluid biological material into or from the container through the first cannula.

Regarding claims 25 and 28, Smith/Vlasselaer teach the device is capable of receiving a hypodermic needle. Therefore the device is also capable of receiving a device where the end of a syringe includes an adaptor including a pierceable membrane and wherein the length of the hollow needle is the same as or less than the height of the container.

Regarding claim 29, Smith/Vlasselaer teach the length of the third cannula is at least equal to the height of the container (Fig. 8).

Regarding claim 30, Smith/Vlasselaer teach the shape of the container is substantially cylindrical (Fig. 1 and 3).

Regarding claim 31, Smith/Vlasselaer teach the shape of the bottom end of the container is substantially tapered (Fig. 1).

Regarding claim 32, Smith/Vlasselaer teach the shape of the bottom end of the container is substantially conical (Fig. 8).

Regarding claim 33, Smith/Vlasselaer teach the shape of the bottom end of the container is substantially frustoconical (Fig. 4).

Regarding claim 34, Smith/Vlasselaer teach the shape of the bottom end of the container is substantially hemispherical (Fig. 6).

Regarding claim 35, Smith/Vlasselaer teach the container further comprises a substantially circular base formed by an extension of the circular wall of the container that extends around the bottom end of the container (Fig. 1: 22).

Regarding claim 36, Smith/Vlasselaer teach the lid is configured to be screwed onto the top end of the container (Para. 0028).

Regarding claim 37, Smith/Vlasselaer teach the container is graduated (Fig. 1).

Response to Arguments

5. Applicant's arguments filed 4/7/2010 have been fully considered but they are not persuasive.

6. Applicants argue that the present invention does not provide or claim an air filter that avoids contamination and that the first hole (3) houses the first cannula (4), which is operationally connected to a seat (5); a tap (6) is arranged between said seat (5) and

said first cannula (4). This tap (6) can be in an opened or closed position. The tap (6) is opened when the material is transferred into/out the container, so as to allow the exit of a volume of air to compensate the entry of a volume of material from the container or to allow the entry of a volume of air to compensate the exit of a volume of material in the container (see pg. 7, lines 28-30 and pg. 8, lines 22-25). The tap (6) is closed when the container is subjected to centrifugation, so that it is no longer necessary to use the removable lid (20). It is noted that the arguments regarding the tap are not within the scope of the claims. Applicant's claim a tap, but no further structure is provided that would define over the filter and tube structure of Vlasselaer that is being read on the tap. It is further noted that "tap" is sufficiently broad to read on any structure that provides access to a closed container.

7. Applicants further argue that the membrane (10) used in the present invention is a pierceable membrane and not a sealable membrane and therefore the sealable membrane of Vlasselaer cannot be read on the pierceable membrane. It is noted that "pierceable membrane" is sufficiently broad to read on any membrane capable of being pierced. Applicants further argue that a pierceable membrane is able to close again by itself, when the needle is removed, which is not taught by the porous septum of Vlasselaer. This argument is not within the scope of the claims. The claims require that the membrane be "pierceable", which is met by the porous septum of Vlasselaer as per above.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DENNIS M. WHITE whose telephone number is (571)270-3747. The examiner can normally be reached on Monday-Thursday, EST 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LYLE A ALEXANDER/
Primary Examiner, Art Unit 1797

/dmw/